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IN THE UNITED STATES DISTRICT COURT
THE DISTRICT OF NEW JERSEY

ASTRAZENECA AB, AKTIEBOLAGET HÄSSLE, ASTRAZENECA LP, KBI INC., and KBI-E INC., Plaintiffs and Counterclaim Defendants, v. HANMI USA, INC., HANMI PHARMACEUTICAL CO., LTD., HANMI FINE CHEMICAL CO., LTD, and HANMI HOLDINGS CO., LTD., Defendants and Counterclaim Plaintiffs.	Civil Action No. 11-760 (JAP)(TJB)

Hanmi's Motion in Limine No .6
(To Preclude AstraZeneca From Attempting To Introduce Evidence On Issues And Theories Not In The Case)

Hanmi hereby moves *in limine* to preclude AstraZeneca's introduction of argument, testimony and documents related to the below subject matter areas that are not a part of this case:

I. Patent Information Forms submitted to FDA in connection with Hanmi's NDA 202342.
II. The status of FDA proceedings and FDA's determinations about Hanmi's Proposed NDA Product.
III. Hanmi's commercial activities concerning launch of its Proposed Product, if approved by FDA.

No theory or claim pertaining to any of the above topics is disclosed in any version of AstraZeneca's contentions or expert reports. Nor has AstraZeneca ever sought leave of this Court to amend its contentions to articulate any theory that would permit presentation of evidence at trial concerning any of the above subject matter. The Local Patent Rules do not permit the addition of new unrelated theories, let alone unarticulated theories, or new evidence on the eve of trial. Local Patent Rule 3.6; *King Pharm., Inc. v. Sandoz Inc*., Case No. 08-5974 (GEB), 2010 WL 2015258, at *4 (D. N.J. May 20, 2010) ("The rules are designed to require parties to crystallize their theories of the case early in the litigation and to adhere to those theories once they have been disclosed."). Parties are required to proceed with diligence in amending contentions. *O2 Micro Int'l, Ltd. v. Monolithic Power Sys., Inc.*, 467 F.3d 1355, 1365-66 (Fed. Cir. 2006). No basis exists for AstraZeneca to bypass the case schedule and procedures set by the Court (D.I. 56, as amended by D.I. 60; L. Pat. R. 3.6 and 3.7.) and to introduce the above subject matter and amorphous theories that have no bearing on this case.

At issue for trial is whether or not the asserted '504 and '192 patent claims are valid and infringed. Subject matter regarding regulatory review, timing of and determinations to be made by the FDA, and Hanmi's business activities concerning commercialization and launch plans do not relate to the questions of infringement and validity of the asserted patent claims. Rather, determinations of infringement or validity here are based on the records developed through discovery, contentions and expert reports. Yet, in its April 19, 2013 pretrial disclosures,

AstraZeneca identifies documents and testimony of Hanmi and its U.S. regulatory consulting agent, Parexel International Corporation ("Parexel") concerning Hanmi's Patent Information Forms, portions of FDA status documents, and testimony concerning Hanmi's marketing efforts and launch plans. (Ex. 22, Excerpts from Plaintiffs' April 19, 2013 Pretrial Disclosures (designating testimony of Hanmi and Parexel 30(b)(6) witnesses, Kyu Chan Kwon and Leslie Devos, and related documents).

AstraZeneca's attempt to inject its previously-undisclosed and, more fundamentally, irrelevant subject matter into the case is in violation of the Local Patent Rules and the Orders of this Court. D.I. 56 as amended by D.I. 60; L. Pat. R. 3.6 and 3.7.; *Jazz Pharm., Inc. v. Roxane Labs.,* Case No. 2:10-CV-06108(ES-CLW), 2012 U.S. Dist. LEXIS 107408, at *8 (D. N.J. July 30, 2012) explaining that the Rules are designed to prevent the "shifting sands approach" to a party's contentions).

I. Patent Information Forms Submitted To FDA In Connection With Hanmi's NDA 202342 Are Not Relevant, And Are Not Cited in Contentions Or Expert Reports

Since the close of fact discovery in November of 2012, AstraZeneca has succeeded in pursuing additional discovery for months (*see e.g.* D.I. 273, 280, D.I. 273, Ex. E (Hanmi's 02-11-2013 First Supplemental Privilege Log); April 12, 2013 letter, M. Tarantino to Judge Bongiovanni submitting documents for *in camera review* and attaching Hanmi's 03-06-2013 Second Supplemental Privilege Log). AstraZeneca has had the 2010 Patent Information Forms in question since the start of this case. Yet its "Patent Information Form infringement theory" was never disclosed in its infringement contentions and AstraZeneca has never sought to amend its contentions to include this unstated theory. ***Consistent with the fact this theory is not a part of AstraZeneca's contentions, it appears nowhere in any expert report to date.*** (*See* D.I. 280, p. 2.)

Hanmi respectfully requests that the Court now preclude AstraZeneca from introducing at trial any subject matter (be it in the form of argument, testimony, the forms themselves or other related documents) concerning Hanmi's Patent Information Forms. If the Court is inclined to permit introduction of the Patent Information Forms – even though not disclosed in AstraZeneca's contentions or expert reports – Hanmi requests preclusion of any testimony or evidence apart from the forms themselves. Introduction of such subject matter at trial will result in waste of time, confusion of the issues and unfair prejudice to Hanmi in direct contravention of Rule 403 of the Federal Rules of Evidence.

II. Status of FDA Proceedings

The status and particulars of proceedings at the FDA are wholly irrelevant to any claim at issue in the present action. The FDA's determination of whether to finally approve Hanmi's Proposed Product will – apart from the expiration of the statutory 30-month stay, or a prior judgment from this Court – be made completely independent of this action. The timing and/or adequacy of FDA's determinations with respect to Hanmi's Proposed Products is not a part of AstraZeneca's case contentions. Yet, in depositions of Mr. Kwon and Ms. Devos, AstraZeneca has insisted on lines of questioning concerning speculations on timing of approval, and the nature of submissions to the FDA. Per AstraZeneca's April 19, 2013 pretrial disclosures, it seeks to introduce such testimony and related documents at trial. (Ex. 22; *see also* Ex. 24-25 (Hanmi's Objections to AstraZeneca's Second and Third 30(b)(6) Notices). This subject matter has nothing to do with the infringement and validity questions at issue in this action. Introduction of such subject matter at trial will result in waste of time, confusion of the issues, and unfair prejudice to Hanmi, again in violation of Fed. R. Evid. 403.

III. Hanmi's Commercial Activities Concerning Launch Of Its Proposed Product, If Approved By FDA

Hanmi's commercial and launch planning activities are not at issue in this case. Hanmi's launch plans and related business activities have no relevance to any matter at issue concerning the upcoming trial. On an April 11, 2013 call with the parties, Judge Bongiovanni denied AstraZeneca's request for launch plan/commercial discovery. *See also* Ex. 26, *AstraZeneca LP v. Breath, Ltd.*, No. 08-01512, ECF Document No. 86, at 3 (D.N.J. filed Sept. 8, 2009) (denying AstraZeneca's request to have the Court enter an order directing Defendant to provide advance notice of any anticipated launch of, or launch plans concerning its product, in part because ***"the Court does not believe it has legal authority to grant such relief."*** (emphasis added); Ex. 27, A*straZeneca LP v. Osmotica Pharms. Corp.,* No. 10-4203, ECF No. 42, at 2 (D.N.J. filed Nov. 16, 2010) (Judge Bongiovanni denying a request for a 45-day advance notice of a planned commercial launch); Ex. 28, *AstraZeneca LP v. Ivax Pharms., Inc.*, No. 05-5142, Trans. of Teleconf. at 10 (D.N.J. July 17, 2008).

AstraZeneca has insisted on questioning of Hanmi and Parexel witnesses, and harassing Hanmi for documents (*see, e.g.,* April 10, 2013 letter, M. Tarantino to Judge Bongiovanni) concerning commercial launch plans with respect to Hanmi's proposed NDA product. And despite Judge Bongiovanni's rulings on April 11, 2013 that launch plans fall outside the confines of this case, AstraZeneca has likewise designated such testimony and related documents in its April 19 pretrial deposition designations and trial exhibit list. Again, the only issues in the case are whether AstraZeneca's asserted claims are valid and infringed. Presentation at trial regarding commercial activities is irrelevant to any issue in the case and in violation of Fed. R. Evid. 403, and will result in waste of time, confusion of the issues and unfair prejudice to Hanmi if raised at trial.

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CERTIFICATE OF SERVICE

I hereby certify that on April 29, 2013, I caused a copy of the foregoing **Hanmi's Motion *in Limine* No .6 (To Preclude AstraZeneca From Attempting To Introduce Evidence On Theories Not In The Case)** to be served upon the following counsel by electronic mail:

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